

Office-Based Surgery Now Regulated

Obligations begin in January 2008.

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BEGINNING in January 2008, physicians who perform certain types of office-based surgery are subject to a new regulatory framework. New §230-D to the Public Health Law requires that all physician offices that perform “office-based surgery” be accredited by an approved accrediting agency by July 14, 2009, and requires reporting of adverse events to the Department of Health starting Jan. 14, 2008 (the “new law”).

Background

While surgical procedures performed in hospitals and ambulatory surgical centers are subject to stringent regulatory standards, the same procedures performed in a physician’s private office were not subject to the same or similar standards.

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In 1997, the New York State Public Health Council and the New York State Department of Health (DOH) appointed an Ad Hoc Committee on Quality Assurance in Office-Based Surgery (Committee). The Committee recommended Clinical Guidelines for Office-Based Surgery (Guidelines).

After a legal challenge, DOH resumed publication and distribution of the Guidelines. They were not regulations, however, and could not be enforced as law or regulation.

The Committee was reconvened in 2005 and its recommendations were issued in the Report of the Committee on Quality Assurance in Office-Based Surgery in July 2006 (Report). The Committee recommended draft legislation, and the new law mirrors that draft with a few minor changes.

The New Law

The new law defines “office-based surgery” as any surgical or other invasive procedure requiring general anesthesia, moderate sedation or deep sedation, and any liposuction procedure.

Excluded are minor procedures per-

formed with local or topical anesthesia. Also excluded is liposuction if less than 500 cc of fat is removed under unsupplemented local anesthesia. Note that “unsupplemented” is not defined. Violating the new law has been added to the definition of professional misconduct in the Education Law.

The new law applies only to physicians, who are regulated by DOH, but the Report recommended that the state education department also adopt the same recommendations for other professions that it regulates (e.g., podiatrists and dentists) so that consumers are assured there will be a single standard of care in office-based surgical practices. The new law requires DOH to promulgate regulations.

Adverse Event Reporting

Beginning on Jan. 14, 2008, physicians and physician assistants are required to report certain adverse events in office-based surgery to the DOH’s Patient Safety Center (PSC) within one business day of the occurrence of the event.

The reports are confidential and exempt from disclosure under the state’s Freedom

of Information Law and from discovery in civil proceedings. The PSC, however, may refer the report directly to the Office of Professional Medical Conduct (OPMC) when appropriate. The adverse events to be reported are:

- (i) patient death within 30 days;
- (ii) unplanned transfer to a hospital;
- (iii) unscheduled hospital admission, within 72 hours of the office-based surgery, for longer than 24 hours; or
- (iv) any other serious or life-threatening event.

Accreditation Requirement

Commencing July 14, 2009, all office-based surgery practices are required to obtain and maintain full accredited status with a nationally recognized accrediting agency, as determined by the Commissioner of Health. As of that date, office-based surgery in a non-accredited office-based practice will be prohibited.

Accreditation, and the requirement for it, applies to the practice as a whole regardless of how many physicians are in the group. Each site performing OBS must be accredited.

Although the Committee consulted with three accrediting agencies in preparing the Report, DOH has not yet designated the specific approved accrediting agencies. The three agencies which DOH consulted are: the Joint Commission, the Accreditation Association for Ambulatory Health Care (AAAHC) and the American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF).

Standards differ among the three agencies, especially with respect to peer review, credentialing/privileging, enforcement and adverse event reporting. Whether DOH will seek to conform standards among the agencies it selects, such as in regulations, has not been announced.

In addition, the three agencies classify facilities by the level of anesthesia pro-

vided, but the classifications are not standardized and the new law uses definitions that may not be the same as those used by the agencies. This should be clarified in future regulations.

DOH must enter into agreements with the approved accrediting agencies pursuant to which the agencies would report aggregate data on adverse events for all office-based surgery practices they accredit. DOH will be permitted to disclose aggregate data to the public.

While adverse event reporting to DOH is confidential under the new law, reports sent to accreditation agencies may not be privileged or confidential under the law. Currently, our understanding is that only one of the major accrediting agencies requires adverse event reporting; how DOH will address requiring the agencies to gather this data and the confidentiality issue remains to be seen.

What Impact on Physicians?

Achieving and maintaining accreditation should increase patient safety, and will be an important quality indicator for patients. But while accreditation lends a practice credibility, preparing for accreditation can be a costly, time-consuming endeavor.

Accreditation standards require an office to have appropriately trained staff and equipment to deal with emergencies, and architectural and physical layout changes to the office may need to be made. Although some of the necessary modifications may be costly, the new law has no impact, in and of itself, on whether physicians can charge a "facility fee," and get higher reimbursement.

DOH has made it clear that the Medicaid program will not pay a facility fee to accredited OBS practices. This does not prohibit OBS practices from contracting for enhanced fees from private insurers. Physicians are well advised to proceed cautiously, however, and obtain

legal counsel before seeking enhanced reimbursement or facility fees from private insurers.

Considering the number of practices that will need to become accredited and the manpower required of these agencies, it is not too soon to start focusing on accreditation requirements and process. While DOH has not yet selected the agencies that will be responsible for accreditation, review of the three major agencies' standards will provide a basis for physicians to select the appropriate agency and begin planning for accreditation.

The reporting requirement is effective in less than one month.